

**International Conference on Harmonization (ICH)**  
**M2 EWG Meeting - Summary**  
**Tysons Corner, VA USA 02 - 05 February 1998**

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Participants:

**EU:** Esteban Gonzalez Juarros, Antonia Rana  
**EFPIA:** Gabriele Disselhoff  
**PhRMA:** Kris Arora, Gary Green (partly), Bob Hizer  
**FDA:** Greg Brolund (Rappoteur), Melissa Chapman, George P George, Robin Jones  
**JPMA:** Hitoshi Asano, Harv Martens, Tomoya Masaki, Yuichi Nagoshi, Isamu Okuno, Keiji Sawamukai, Tohru Uwoi (partly)  
**MHW:** Daisuke Koide (partly), Mihoko Okada  
**Observer:** Bob Kapitany (Health Canada) (partly)

The tasks accomplished and the decisions agreed are the following:

The ICH M2 working web site was demonstrated to the Steering Committee. This demonstration included the facilities for the exchange of information among the members of the Working Groups by means of Discussion Fora and Mailing lists.

The M2 Notebook was finalized and distributed to the Steering Committee.

The specification of the change control process to manage modifications to ESTRI standards was finalized. The procedure defined in this document will be followed by the M2 EWG until a formal maintenance organization is established. The document will be placed on the M2 Web site <http://www.ifpma.org/m2-site/m2-main.html>.

The Steering Committee agreed to sign the message definition for the electronic transmission of Individual Case Safety Reports: ICH\_ICSR DTD v.1.0.

The key activities to be undertaken were discussed and will be prioritized. They are:

- Provision of recommendations for the Secure Correspondence between regulators and Industry
- Investigation of the need for electronic tracking of Individual Case Safety Reports including the specification of unique identification of reports.
- Investigation of solutions for the transmission of safety reports in multiple languages.
- Provision of a method for effective interaction with the CTD EWGs: Quality, Safety and Efficacy.
- Provision of recommendations for the acknowledgement of receipt of Individual Case Safety Reports.
- Support for the Common Technical Documents electronic transmission of E2C reports.
- Support to the usage of MedDRA for the electronic transmission of Individual Case Safety Reports

M2 contacts for the three CTD groups have been nominated EFPIA (Gabriele Disselhoff) for Quality, JPMA (Keiji Sawamukai) for Safety, and PhRMA (Kris Arora) for Efficacy. It was agreed with the CTD groups that contacts would obtain the working documents of the groups and discuss them at the next meeting.

An interim meeting of the M2 EWG was tentatively agreed for May 1998 in Japan.